

REMARKS

This communication responds to the Office Action of September 27, 2007, in which the Examiner rejected claims 1-6, 8, 9, 12, 13, 17 and 19. The drawings were objected to and claims 6, 9, 12 and 13 were objected to for informalities.

Drawings

The Drawings were objected to under 37 C.F.R. § 1.83(a). Specifically, the Examiner objected to the drawings because the operating means pivotable in a radial direction relative to the casing about a fulcrum and wherein the protrusion is co-operable with the piston rod via a surface oblique relative to a longitudinal axis, as claimed in claims 1 and 17, and a releasing element projecting through an opening in the casing of the injection device where the dimensions of the opening limit movement of the releasing element, as claimed in claims 6 and 17, must be shown or the features canceled from the claims.

Applicants respectfully assert that all such features are shown in figures 1-8. Specifically, Figure 1 illustrates an operating means 7 pivotable in a radial direction relative to a casing 3 about a fulcrum 10 and wherein the protrusion 9 of the operating means 7 is co-operable with a piston rod 5, 6 via a surface 11 oblique relative to a longitudinal access. Furthermore, Figure 2e illustrates a releasing element 50 projecting through an opening 52 of the injection device where the dimensions of the opening (first stopper 54 and second stopper 55) limit movement of the releasing element 50.

Reconsideration and withdrawal of the objections are requested.

Claim Objections

Claims 6, 9, 12 and 13 were objected to for informalities. Specifically, the Examiner asserts that there is insufficient antecedent basis for the limitation "said fluid product" in claims 6 and 13 and suggests that "said fluid product" be replaced with "the fluid product." Applicants respectfully assert that "a fluid product" is positively recited in the preamble of claim 6, providing sufficient antecedent basis for "said fluid product." Furthermore, Applicants respectfully assert that "said fluid product" is equivalent to "the fluid product" and thus the

Examiner's suggested change would not overcome a proper objection for lack of antecedent basis. *MPEP*, section 2173.05(e)

Rejection under 35 U.S.C. § 112

Claim 13 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claim 13, obviating the rejection thereof. Reconsideration and withdrawal of the rejection are requested.

Rejections under 35 U.S.C. § 102

Claims 1-5, 17 and 19 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,444,560 ("Jacklich").

Independent Claim 1 is Not Anticipated by Jacklich

Claim 1 recites an injection device for administering a fluid product comprising, in part, an "operating means for operating said piston rod... said operating means having a lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device."

Jacklich does not disclose the invention of claim 1 at least because it does not disclose an "operating means having a lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device."

Jacklich discloses a compact anesthetic syringe. As can be seen with reference to figures 1-2, the syringe includes an operating handle 53 coupled to a ratchet 57. The ratchet 57 is pivoted on the handle 53 and a spring 55 biases the ratchet 57 into a groove 49. *Jacklich*, col. 2, ll. 23 – 27. The syringe also includes a piston rod 61 having a number of ratchet teeth 63. *Jacklich*, col. 2, ll. 28 – 30. In operation, as the handle 53 is worked back and forth, the piston rod 61 will advance into the cylinder. *Jacklich*, col. 2, ll. 35 – 37. As can be seen with reference to figures 1-2, such advancement is achieved by the ratchet 57, extending at an acute angle from the operating handle 53, engaging the ratchet teeth 63 of the piston rod 61. Also, as can be appreciated by reference to figures 1-2, advancement of the piston rod 61 could not occur if the ratchet 57 extended from the operating handle 53 at any angle other than an acute angle .

Specifically, advancement of the piston rod 61 could not occur if the ratchet 57 extended substantially perpendicular from the operating handle 53.

Accordingly, Jacklich does not disclose an “operating means having a lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device,” as recited in claim 1. Reconsideration and withdrawal of the rejection are requested.

Independent Claim 17 is Not Anticipated by Jacklich

Claim 17 recites an injection device comprising, in part, “a releasing element for releasing a dosage amount to be dispensed by the injection device, wherein the releasing element projects through an opening in the casing of the injection device, and dimensions of the opening limit movement of the releasing element, thereby determining the dosage amount to be dispensed, wherein the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side.”

Jacklich does not disclose the invention of claim 17 at least because it does not disclose “wherein the wherein the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side.”

In the Office Action of September 27, 2007, the Examiner asserts that the device of Jacklich discloses “a releasing element (57) for releasing a dosage amount.” *Office Action*, page 5. As discussed above, and with reference to figures 1-2, Jacklich discloses a ratchet 57 which extends through an opening in the casing 9 and engages the piston rod 61.

Assuming, for purposes of argument, that the ratchet 57 of the device of Jacklich may be properly characterized as a releasing element, the Examiner has failed to identify a first stopper on a first side of the opening and a second stopper on a second side of the opening. Applicants respectfully assert that Jacklich does not disclose such elements. As can be seen with reference to figure 2, at most, the ratchet 57 may be moved to a first stopper 49 on a side of the opening. At no time during operation of the device does the ratchet 57 contact any other portion of the casing 9.

Accordingly, Jacklich does not disclose an “wherein the wherein the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a

second stopper on a second side of the opening, opposite the first side,” as recited in claim 17. Reconsideration and withdrawal of the rejection are requested.

Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,575,939 (“Brunel”).

Independent Claim 6 is Not Anticipated by Brunel

Claim 6, as amended, recites an injection device for administering a fluid product comprising, in part, “dosing means for releasing a predetermined amount of a dosage . . . wherein said dosing means comprises a releasing element for releasing the dosage, wherein the releasing element projects radially through an opening in the casing of the injection device, and dimensions of said opening limit movement of the releasing element, thereby setting the predetermined amount of the dosage.”

Brunel does not disclose the invention of claim 1 at least because it does not disclose “wherein said dosing means comprises a releasing element for releasing the dosage, wherein the releasing element projects radially through an opening in the casing of the injection device, and dimensions of said opening limit movement of the releasing element, thereby setting the predetermined amount of the dosage.”

Brunel discloses a device for automatically injecting a dose of a medicinal product. The device includes a sleeve 12 provided with a trigger 15 in its peripheral wall. *Brunel*, col. 6, ll. 1-4. The trigger 15 has a longitudinal bar 15a oriented in the direction of the rear end of the sleeve 12 and is adapted so that when pressed by a finger, the transverse member 15b retracts inside the sleeve. *Brunel*, col. 6, ll. 5-10. The sleeve 12 may be situated in a retracted position (figure 14) in which actuation of the trigger 15 is prevented, or in a forward position (figure 15) in which actuation of the trigger 15 is enabled. *Brunel*, col. 8, ll. 35 – 63. Injection of the medicinal product is obtained by actuating the trigger 15 which leads to a deformation of a tongue 39 and freeing of a stirrup 35, which in turn, initiates a cascade of events culminating in injection and complete emptying of the product. *Brunel*, col. 8, l. 64 – col. 9, l. 10.

As an initial matter, the trigger 15 does not project radially through an opening of the device of Brunel, but rather, is formed integrally on the sleeve 12 in a longitudinal direction.

Assuming, however, for purposes of argument that the trigger 15 may be properly characterized as projecting radially through an opening, Brunel still does not disclose the invention of claim 6 because actuation/movement of the trigger 15 does not set an amount of

dosage to be injected. Rather, as described above, actuation of trigger 15 initiates a cascade of events which result in injection and complete emptying of the product.

Accordingly, Brunel does not disclose “wherein said dosing means comprises a releasing element for releasing the dosage, wherein the releasing element projects radially through an opening in the casing of the injection device, and dimensions of said opening limit movement of the releasing element, thereby setting the predetermined amount of the dosage,” as recited in claim 6. Reconsideration and withdrawal of the rejection are requested.

Claim 13 was rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Published App. No. 2003/0144632 (“Hommann”).

Independent Claim 13 is Not Anticipated by Hommann

Claim 13, as amended, recites an injection device for administering a fluid product comprising, in part, “a casing, a holder for a product container of said fluid product, an injection needle, and a needle protector . . . wherein the holder for the product container . . . is insertable into the casing and removable from the casing to exchange the product container.”

Hommann does not disclose the invention of claim 1 at least because it does not disclose “a holder for a product container of said fluid product . . . wherein the holder for the product container . . . is insertable into the casing and removable from the casing to exchange the product container.”

Hommann discloses an injection device. The device comprises a casing 12, an ampoule 14 having an injection needle 16 and a discharge piston 18, and a needle protecting sleeve 20. *Hommann*, paragraph [0031]. The ampoule 14 is held by the casing such that the ampoule 14 together with the injection needle 16 and piston 18 can be removed from the casing and disposed of. *Hommann*, paragraphs [0031], [0049]. Hommann does not disclose a holder for the ampoule. Thus, Hommann cannot disclose wherein a holder for the ampoule is insertable into and removable from the casing. Furthermore, to the extent the casing 12 can be characterized as a holder for the ampoule, the casing 12 is not capable of insertion and removal into and from itself, and thus cannot anticipate the holder for a product container as claimed in claim 13.

Accordingly, Hommann does not disclose “a holder for a product container of said fluid product . . . wherein the holder for the product container . . . is insertable into the casing and removable from the casing to exchange the product container,” as recited in claim 13. Reconsideration and withdrawal of the rejection are requested.

Claims Depending From Claims 1, 6, 13 and 17 are Patentable

The remaining claims depend either directly or indirectly from independent claims 1, 6, 13 or 17 and incorporate all the limitations thereof. Accordingly, these claims are also patentable for at least for the reasons presented above. Reconsideration and withdrawal of the rejections are requested.

Conclusion

No additional fees should be due in connection with this communication. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application is in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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